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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| LEWIS, AARON J | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 3743 | |

DATE MAILED: 12/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/615,953 | GRAD ET AL. | |
| | Examiner | Art Unit | |
| | AARON J. LEWIS | 3743 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *10 July 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 1-10,14,15 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie et al. ('120) in view of Ruiz ('261).

As to claim 1, McKenzie et al. (e.g. figs.2 and 4) disclose implantable device (10) implantable in an artery of a patient at a bifurcation thereof into a first branch supplying blood to a vital region having a high sensitivity to emboli in the blood, and a second branch supplying blood to a less vital region having a lower sensitivity to emboli in the blood; said implantable device being of tubular configuration (col.10, lines 16-21) initially of a small diameter for facilitating its introduction into and deployment through the artery to said bifurcation, and expandable to a larger diameter for implantation in the artery at said bifurcation; said implantable device comprising: a base element configured and dimensioned for anchoring said implantation device in the artery at said bifurcation (col.9, lines 5-15), and a deflector element (25) configured and dimensioned for covering the inlet of said first branch at the bifurcation when the implantable device is implanted in said artery; said deflector element being formed with openings therethrough of a size and configuration to deflect emboli in the blood to said second

branch without blocking blood flow through said second branch or through said first branch (col.9, lines 30-67).

The difference between McKenzie et al. and claim 1 is said base element being a coil of tubular configuration having overlapping ends in said initial diameter enabling it to be expanded from said initial diameter to said larger diameter.

Ruiz, in an implantable device implantable in an artery of a patient at a bifurcation, teaches a base element being a coil of tubular configuration having overlapping ends in said initial diameter enabling it to be expanded from said initial diameter to said larger diameter for the purpose of enabling ready and safe removal of the device (col.2, lines 12-18 and lines 39-42) enabling the device to be wound down to a small diameter for transluminal delivery and expanded to engage the interior walls of arteries of various diameters (col.3, lines 38-43).

It would have been obvious to modify the configuration of the device of McKenzie et al. to have overlapping ends because it would have enabled ready and safe removal of the device enabling the device to be wound down to a small diameter for transluminal delivery and expanded to engage the interior walls of arteries of various diameters as taught by Ruiz.

As to claim 2, McKenzie et al. as modified by Ruiz (e.g. figs.1A,1B) disclose said coil is a perforated sheet coiled into said tubular configuration.

As to claim 3, Ruiz (fig.1A and col.2, lines 62-65) teaches said perforated sheet is dimensioned also to have overlapping ends when expanded to said larger diameter.

As to claim 4, Ruiz (fig.1A and col.2, lines 62-65) teaches said perforated sheet is dimensioned to define a gap between its ends when expanded to said larger diameter.

As to claim 5, McKenzie et al. disclose deflector element (25) is integrally formed with said perforated sheet.

As to claim 6, McKenzie et al. disclose said perforated sheet of the base element (50) is formed with larger size openings than those (e.g. 70) of said deflector element (25).

As to claim 7, McKenzie et al. disclose said perforated sheet of the base element is formed with a relatively stiff frame (50) around its periphery.

As to claims 8 and 9, while McKenzie et al. do not expressly disclose a particular diameter nor range of diameters for the implantable device while in its compressed and expanded states, there is express disclosure that the implantable device can be sized to fit vessels of varying sizes (col.6, lines 27-28); therefore, it would have been obvious that the implantable device of McKenzie et al. as modified by Ruiz is sized in accordance with the vessel into which it is intended for placement and would have required various sizes including 1-4mm (compressed) and 5-30mm (expanded) to accommodate the various vessel sizes within a human body.

As to claim 10, McKenzie et al. (col.9, lines 30-35) disclose said perforated sheet of the base element and said deflector element are both of a mesh material, woven material each of which is readable upon a braided material.

As to claim 14, McKenzie et al. discloses wire supports (col.12, lines 37-43). An inherent feature of wire is its radiopacity; accordingly, said perforated sheet of the base element includes at least one radiographic opaque marker.

As to claim 15, while McKenzie et al. (e.g. figs.2 and 4) do not expressly disclose nor illustrate the implantable device being configured and dimensioned for implantation into a patient's CCA at its bifurcation into the ICA constituting said first branch, and the ECA constituting said second branch, given the level of skill in the art it would have been obvious to employ the overall teachings of the disclosure to employ the deflector of McKenzie et al. to block the flow of embolic material from any of the carotid arteries at a bifurcation including the internal carotid artery at the bifurcation of the common carotid artery, internal and external carotid arteries.

3. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over McKenzie et al. ('120) in view of Ruiz ('261) as applied to claims 1-10,14 above, and further in view of Daniel et al. ('932) and Barbut et al. ('555).

The difference between McKenzie et al. as modified by Ruiz and claim 11 is said perforated sheet of the base element is constructed of wires having a diameter of 100-1500 microns.

Daniel et al., in a vascular filter, teach an equivalency between a plurality of materials (including wires) from which a filtering portion (22) is made (col.3, lines 31-33).

It would have been obvious to make the filtering mesh of McKenzie et al. from any one of a plurality of materials including wires as mere substitution of one well known functionally equivalent material for another as taught by Daniel et al..

Barbut et al. teach the variance of the physical parameters of a filtering mesh (40) in dependence upon the sizes of the particles that are intended to be trapped (col.9 line 9-col.11, line 44).

It would have been obvious to modify the physical parameters of the mesh of McKenzie et al. as modified by Daniel et al. including thickness of the wire of the mesh because the of the necessity of constructing a filter based upon the sizes of the particles to be trapped as taught by Barbut et al..

As to claims 12 and 13, Barbut et al. as discussed above, teach the adjustment of the sizes of the wire in dependence upon the sizes of the particles to be trapped; therefore, it would have been obvious to vary the sizes of the wire mesh of the device to a variety of sizes including a diameter of 100-200 microns and a diameter of 20-75 microns depending upon the particle sizes intended to be trapped.

***Double Patenting***

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 16-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5-24 of U.S. Patent No. 6,673,089 in view of Ruiz ('261).

The difference between the invention of patent claim 5 and instant application claim 16 is a base element being a coil of tubular configuration having overlapping ends in said initial diameter enabling it to be expanded from said initial diameter to said larger diameter.

Ruiz, in an implantable device implantable in an artery of a patient at a bifurcation, teaches a base element being a coil of tubular configuration having overlapping ends in said initial diameter enabling it to be expanded from said initial diameter to said larger diameter for the purpose of enabling ready and safe removal of the device (col.2, lines 12-18 and lines 39-42) enabling the device to be wound down to a small diameter for transluminal delivery and expanded to engage the interior walls of arteries of various diameters (col.3, lines 38-43).

It would have been obvious to modify the configuration of the device defined by patent claim 5 to have overlapping ends because it would have enabled ready and safe removal of the device enabling the device to be wound down to a small diameter for transluminal delivery and expanded to engage the interior walls of arteries of various diameters as taught by Ruiz.

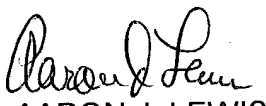
***Conclusion***

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The balance of the art is cited to show relevant implantable devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to AARON J. LEWIS whose telephone number is (571) 272-4795. The examiner can normally be reached on 9:30AM-6:00PM M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, HENRY A. BENNETT can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



AARON J. LEWIS
Primary Examiner
Art Unit 3743

Aaron J. Lewis
November 21, 2004